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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,657	12/01/2004	Hajime Yamada	P/2850-101	8759

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EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	
ART UNIT	PAPER NUMBER
1611	
MAIL DATE	DELIVERY MODE
09/11/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/516,657	YAMADA ET AL.	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Amendment and response all filed 7-6-09 is acknowledged.

Claims 1 and 3-9 are pending.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7-6-09 has been entered.

The following is new rejection:

Claims 1, 3 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites at least one grape sugar, mutan, lentinan, sodium chloride, and potassium chloride. It is unclear if the claims require at least one sugar and also all the other components such as mutan, lentinan, sodium chloride, and potassium chloride or at least one selected from the group consisting of grape sugar, mutan, lentinan, sodium chloride, and potassium chloride. From a review of claim 5, it appears that the claim requires only one of the components. A clarification and a correction is required.

In response to the arguments, the following rejection of record has been withdrawn:

Claim 1 and 3-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0780129 to Yamada et al in view of Griesbach et al (6,875,754), JP 10025240 and in further view of Schmidt et al (5,578,300).

Upon consideration, the following new rejection has been applied to the instant claims:

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 1 and 3-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0780129 to Yamada et al in view of Griesbach et al (6,875,754), JP 10025240, Schmidt et al (5,578,300), Kludas (5,547,997) and Yvin (5,980,916) as evidenced by EP 0668072 to Kludas.

Yamada et al teach a composition for dermatitis comprising an adrenal cortical steroid, cyclodextrin to solubilize the steroid, and water. The composition comprises 0.025-0.5% adrenal cortical steroid; 0.2-30% cyclodextrin; 0.5-55% of dextran or pullan; and an aqueous solution. The solution may further comprise glucose, mutan, lentinan, sodium chloride, and potassium chloride, and other polysaccharides. Yamada discloses all of the skin conditions that are claimed in the instant invention (see table 1) and

shows that the composition is 90% effective in treating the claimed conditions. Yamada et al do not teach xyloglucan (beta-glucan), trehalose, laminaran (beta-glucan), krestin (beta-glucan), and pectin.

Griesbach et al teach the use of water-soluble beta-glucans as therapeutic agents for skin diseases such as dermatitis, cradle cap, psoriasis, seborrhea sicca, seborrhea oleosa, psoriasis vulgaris, ichtyoses or UV erythemas. See column 3, lines 1-10. The glucans are used in an amount of 0.1-25% and preferably 0.5-15%. See column 3, lines 10-15. Specific glucan include krestin. See table 2. Griesbach teaches away from glucans with 1-6 linkages and thus excludes xyloglucan. The reference also fails to teach laminaran.

Kludas teaches compositions for repair and remodelling of aged and damaged skin, to restore the normal physiological interactions and functioning between various layers of skin (col. 5, L-34-col. 6, L 12). The composition of Kludas comprises pectin, xyloglucan, glucan, cellulose and other plant extracellular matrix components. In particular, Kludas teaches the composition being effective for the treatment of skin and improves luminosity moisturization, satinity and skin elasticity (col. 13, L 9-13), and also states that the above polymers that constitute the carbohydrate polymers of the plant extracellular matrix com (claim 16) repair the damaged dermo-epidermal surface of the skin such that the skin condition is healthy and enhanced because the polymers restore normal physiological function of dermis and epidermis and also improve interaction between layers of skin. Kludas does not state xyloglucan for treating atopic dermatitis or psoriasis. However, EP 0668072 (also to Kludas), teaches compositions for repair and remodelling of aged and damaged skin, to restore the normal physiological interactions

and functioning between various layers of skin (page 3, L 27-37 and page 4, L 23-31). The composition of Kludas comprises pectin, xyloglucan, glucan, cellulose and other plant extracellular matrix components (see page 5, L 41-44 and claim 5). In particular, Kludas teaches the composition being effective for the treatment of conditions such as dermatitis, wound healing, skin damage due to corticosteroids, etc (claim 16). Thus, it is implicit that the composition of Kludas comprising xyloglucan, pectin and other glucans are effective for instant treatment of atopic dermatitis.

Yvin teaches a cosmetic, particularly dermatological, composition comprising effective amounts of laminarin or laminarin-derived oligosaccharides as the active agent for stimulating, regenerating, conditioning and energizing effects on human dermis fibroblasts and human epidermis keratinocytes (abstract, col. 2, L 3-10). Yvin teaches that laminarin can be present in the amounts of 0.00001% to 10% (examples 4-6 and col. 3, L 9-13). While Yvin does not teach laminarin for atopic dermatitis or psoriasis, Yvin teaches that laminarin is capable of stimulating and regenerating dermal fibroblasts and keratinocytes, which is also desired in treating conditions such as atopic dermatitis and psoriasis (see Kludas EP reference which teaches that the ability to repair and remodel dermal and epidermal surfaces leads to visible improvement in the appearance of skin and is beneficial in treating conditions such as dermatitis).

JP '240 while teaching a bath agent teach the use of saccharides such as **glucose,** fructose, sucrose, mannitol, sorbitol, maltitol, xylitol, glucuronic acid, **trehalose**, alginic acid, hyaluronic acid, ribose, arabinose and deoxyribose. Ribose, arabinose and trehalose are preferred used in an amount of 1-100%. JP '240 teaches

saccharides have skin moisture retention and are particularly suitable for treatment and prevention of skin diseases including **dermatitis**. See abstract.

Schmidt teaches a method of treating dermatitis using polysaccharides especially pectin in an amount of 0.05-0.5%. See abstract and column 2, lines 50-55. It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Yamada et al, Griesbach, JP '240, Kludas, Yvin et al and Schmidt et al and arrive at the instant invention. One would have been motivated to add beta-soluble glucans such as xyloglucan and pectin (Kludas), laminaran (Yvin), and krestin (Griesbach) to Yamada's composition with a reasonable expectation of success since Greisbach teaches beta-glucans treat skin disorders such as dermatitis because Griesbach and Kludas suggest the claimed glucans for skin conditions such as dermatitis and Yvin teaches that laminarin provide regeneration of damaged dermal and epidermal layers of skin. One would have been motivated to also add pectin in the Yamada's composition with a reasonable expectation of success since Schmidt teaches polysaccharides such as pectin treat dermatitis and Yamada suggests the incorporation of polysaccharides in addition to dextran or pullan. Therefore, it is prima facie obvious to further include active compounds that treat dermatitis for an additive effect. Note In re Kerkohoven. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute Yamada's glucose with the instant trehalose. One would have been motivated to do so with a reasonable expectation of success since Schmidt teach saccharides such as glucose and trehalose treat dermatitis. Therefore, it is prima facie obvious for a skilled artisan to substitute one functional equivalent agent for another since the prior art establishes its functional equivalency.

Response to Arguments

Applicants' arguments dated 7-6-096 have been considered but not found persuasive. Applicants argue that the previous arguments are incorporated by reference. However, the arguments of 11-4-08 have been addressed by the examiner on 3-3-09 and are incorporated by reference herewith. Additionally, the instant rejection now includes new references Kludas and Yvin et al for teaching the glucans, xyloglucan and laminarin. It is argued that Yamada does not teach the materials of claim 1 such as xyloglucan, trehalose, laminarin, pectin and krestin etc. Examiner maintains that the claimed materials are taught by secondary references and that the rejection is over a combination and not on Yamada alone.

Applicants submit, that the unexpectedly improved results achieved with the compositions according to the present invention (i.e., as compared to that disclosed by Yamada et al.) directly contradict the Examiner's finding of 'obviousness' That is, as pointed out in applicants' prior response, the composition as recited in the present claims provides a significant and unexpected improvement in the treatment of atopic dermatitis and psoriasis vulgaris over that disclosed by Yamada et al.. More particularly,

the cited Yamada et al. reference discloses an effective rate against atopic dermatitis that was only about 95% on average, whereas the rate obtained with regard to psoriasis vulgaris was only about 90% on average. In the case of the presently claimed composition, however, as taught in the present application effective rates of around 99% were obtained (see, e.g., Table 3 on p. 13). Applicants' arguments and the unexpected results are not persuasive because firstly, while Yamada teaches 90% efficacy, the efficacy is only limited to the components taught by Yamada, which admittedly lack the components such as trehalose and other glucans of instant claims. If applicants argue that the increase in efficacy to 99% is obtained unexpectedly, it is examiner's position that the effect is not unexpected because the secondary references such as Griesbach, Kludas and JP 240 teach the claimed components for the same purposes i.e., dermatitis and the combination of the teachings of secondary references with that of Yamada would have produced the argued unexpected results because all of the said references teach for the same condition claimed.

It is argued that examiner does not appear to give weight to unexpected results because examiner argued that instant claims do not recite percentage of effectiveness. While it is not necessary to recite the effective percentages in the claims, the examiner maintains the position that the results are not unexpected in view of the combination of prior art teachings and also do not show statistical significance.

It is argued that Griesbach teaches away from glucans with 1-6 linkages and that laminarin and xyloglucan contain 1-6 linkages. On one hand Applicants arguments that the results of Griesbach do not show effectiveness with glucan having 1-6 linkages and

on the other hand, it is argued that the results are pertinent to beauty treatment and not treating dermatitis and psoriasis. However, examiner maintains that even with 1-6 linkages, the beta glucans show significant activity (treatment of skin aging tested by Griesbach). Further, Griesbach has been cited for Krestin and not xyloglucan or laminarin, which is taught by other references that are newly cited in this action. Further, if applicants argue that xyloglucan and laminarin according to prior art are not desirable, it is the position of the examiner that applicants only show a collective effect of the glucans in treating atopic dermatitis and psoriasis but not the effect of each of the claimed glucans. Further, applicants argue that the results of Table 2 cannot be extrapolated to atopic dermatitis. However, Greisbach not only teach beauty treatment but also suggests the role of glucans such as krestin in treating dermatitis and psoriasis (col. 3, L 1-25).

Applicants concede that JP '240 discloses that trehalose may be used in a bath powder and that the powder may be used in the treatment of atopic dermatitis and psoriasis. However, it is argued that the subject reference entirely fails to disclose an effective range of such trehalose and, in particular, that recited in applicants' present composition and method claims. Furthermore, applicants continue to maintain their previously expressed position that it would not be obvious to combine JP '240 which relates to a bath powder with Yamada et al which concerns an external medicine used to treat dermatitis. Further in support of this position is the issue of the unexpected improvement offered with the compositions and methods of the present invention (see the discussion above) which represents an additional factor supporting applicants' contention that it would not be obvious to make the cited combination relied upon to

reject the present claims. Applicants' arguments are not persuasive because JP 240 clearly teaches active agents in the range of 1-100 wt% and applicants have not provided any evidence showing that the claimed amounts are effective whereas outside the claimed range trehalose is ineffective in treating dermatitis. A skilled artisan would have expected trehalose to treat dermatitis in any amount between 1-100% suggested by JP 240. Applicanst have not shown how or why the trehalose taught in a bathing agent cannot be added in a topical composition. The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

It is argued that Schmidt teaches allergic contact dermatitis wherein a hydrogen peroxide generating a polymeric material comprising gelatin and pectin is used to induce an oxidative stress and obtain a heat shock response. Schmidt thus utilizes the composition(s) disclosed therein differently than in the case of the presently claimed composition/method. It is argued that Schmidt, thus, does not disclose an external medicine for treating atopic dermatitis and/or psoriasis vulgaris. Applicants' arguments are not persuasive because instant rejection not only cites Schmidt but also cites Kludas EP (evidence) for treating dermatitis with pectin. Thus, pectin while effective to induce an oxidative stress and obtain a heat shock response also is effective for dermatitis treatment as shown by Kludas (EP).

Furthermore, it is argued Schmidt fails to disclose various components of applicants' claimed composition that are missing from Yamada et al., namely xyloglucan, laminaran, krestin and pectin, including the amounts of these materials

recited in the presently pending claims. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this regard, the examiner cited various secondary references for the teaching of xyloglucan, laminaran, krestin. Thus, the rejection is not over Schmidt alone and is over a combination of references. Thus, in contrast to applicants' arguments that the closest work related to their invention is Yamada references, the other prior art also teaches various methods and compositions for treating the claimed conditions and hence the combination of the cited teachings render the instant composition as well as the method obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

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/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611

September 10, 2009